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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/336,328	06/18/1999	PATRICK J. BURNS	S0351/186588	7500

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EXAMINER	
MONDESI, ROBERT B	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/336,328	BURNS, PATRICK J.	
	Examiner	Art Unit	
	Robert B Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 June 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to amendment filed May 12, 2003. **Claims 1-17** as drawn to elected Invention I are currently pending and are under examination

Maintenance of Rejections and Objections

Specification

The specification is objected to regarding the use of the terms "analogs" and "agonists" interchangeably. On page 6, line 22, of the specification analog is selected from deslorelin--", whereas on page 10, Table 1, deslorelin is cited amongst agonists. Applicant is advised to remain consistent and adopt one terminology throughout to avoid confusion.

Applicant did not respond to the above objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "analogs or agonists" render the claims indefinite as to the claims' metes and bounds. How do "analogs" differ from "agonists"?

Claims 11 and 12 are duplicative of claim 1 being drawn to the same composition.

Response to Arguments

Applicants urge that the Examiner sees no difference between an agonist or an analog and that an agonist is a chemical substance that is capable of combining with a receptor and initiating a reaction, whereas an analog is a chemical compound that is structurally similar to another. The applicants urge further that there does not appear to be any significant overlap between the mentioned terms, and as a result the applicants are justified in using them in the same claim.

The applicant is reminded that the confusion arises from the specification of the application wherein the applicant has categorized the same compound to be both an agonist and an analog. On page 6, line 22, of the specification an analog is selected from deslorelin--", whereas on page 10, Table 1, deslorelin is cited amongst agonists.

Furthermore, in the amendment filed the applicant has not informed the examiner as to where the mentioned definitions of analog and agonist are obtained. The following are definitions of the mentioned terms provided by Stedman's medical dictionary:

Analog: 1. One of two organs or parts in different species of animals or plants, which differ in structure or development but are similar in function. 2. A compound that resembles another in structure, such as an isomer (page 33).

Agonist: 1. Denoting a muscle in a state of contraction, with reference to its opposing muscle, or antagonist. 2. A drug capable of combining with receptors to initiate drug actions; possesses affinity and intrinsic activity (page 19).

So, in view of Stedman's dictionary, it is prudent to note that there is more than one definition for a the mentioned terms, but for the sake of applicants argument lets assume that the definitions provided by the applicant in the amendment, and not in the specification, are considered. If a compound is an analog of another, even though it may not share the structure it may have the same function, and if the original compound is an agonist and is capable of blocking an enzymatic reaction by combining with enzymes then the compound that is its analog will also have the same function (e.g., isopropyl thiogalactoside vs lactose) and hence, a compound can be both an analog and an agonist. Furthermore, some analogs might be agonists and vice versa and they are not mutually exclusive. That is where the confusion comes from. An analog could also be an antagonist and one of skill in the art probably would not use an agonist and an antagonist together. Therefore due to the significant overlap of function between agonist and analog it would not be possible to know the metes and bounds of the invention as claimed in claims 1-17 of the present application.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re*

Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-6 and 8-10 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-6 and 8-10 of prior U.S. Patent No. 6,051, 558. This is a double patenting rejection.

Response to Arguments

The applicants urge "the claims are not identical, and that one could infringe one of the claims without infringing the other (by a composition containing sufficient GnRH, analog, agonist, or combination, to treat a reproductive disorder in, e.g., a pig, and that this would be a different composition from that of the claims of the '558 patent, which would be infringed by a composition containing sufficient GnRH to induce ovulation in mares.) ".

In response to applicant's arguments, the recitation of method of use in the mentioned claims has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

The examiner would also like to point out that the mentioned claim is a product claim (composition claim), therefore the use of the composition, in such claims, does not hold patentable weight absent a specified therapeutic effective amount. As claimed the composition used to treat a reproductive disorder in a pig is not any different than the composition used to induce ovulation in mares. Without disclosing a therapeutic effective amount, a composition used to treat a reproductive disorder in a pig is not patentable over the same composition used to induce ovulation in mares.

The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978) (Claims 1 and 6, directed to a method of effecting nonaddictive analgesia (pain reduction) in animals, were found to be anticipated by the applied prior art which disclosed the same compounds for effecting analgesia but which was silent as to addiction. The court upheld the rejection and stated that the applicants had merely found a new property of the compound and such a discovery did not constitute a new use. The court went on to reverse the rejection of claims 2-5 and 7-10 which recited a process of using a new compound. The court relied on evidence showing that the nonaddictive property of the new compound was unexpected.). See also *In re Tomlinson*, 363 F.2d 928, 150 USPQ 623 (CCPA 1966) (The claim was directed to a process of inhibiting light degradation of polypropylene by mixing it with one of a genus of compounds, including nickel dithiocarbamate. A reference taught mixing polypropylene with nickel dithiocarbamate to lower heat degradation. The court held that the claims read on the obvious process of mixing polypropylene with the nickel dithiocarbamate and that the preamble of the claim was merely directed to the result of mixing the two materials. "While the references do not show a specific recognition of that result, its discovery by appellants is tantamount only to finding a property in the old composition." 363 F.2d at 934, 150 USPQ at 628 (emphasis in original).).

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RBM

Robert B. Mondesi
Patent Examiner
Art Unit 1653
03-20-04

ROBERT A. WAX
PRIMARY EXAMINER